VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/09/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Kathleen Boland, Pharm.D.
Rich Harvie, R.Ph.
Norman Ward, M.D.
Cheryl Gibson, M.D.
Lynne Vezina, R.Ph.
Frank Landry, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Jennifer Mullikin, OVHA
Erin Reisfeld, M.D., OVHA
Nancy Miner, (MHP)
Robin Farnsworth, OVHA
David Calabrese, R.Ph., (MHP)
Stacey Baker, OVHA

Guests:

Amy Finn. Merck
Andy Ritter, Purdue
Angelo Valeri, Novartis
Carl Marchand, AstraZeneca
Dan Doucette, Purdue
David Canepa, Schering Plough
Ed MacMillan, Abbott Diabetes
James ONeil, Novartis
Mark Kaplan, Abbott
Mike Day, Ferndale Labs
Nate Capone, Shire
Renee Hagerty, Takeda
Scott Mosher, GSK
Steve Adams, Sanofi-Aventis

Michael Scovner, M.D., Chair, called the meeting to order at 7:04 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The September 2007 meeting minutes were accepted as printed.

Public Comment: *Scott Mosher, GSK:* Pointed out that the words "or tolerate" had been omitted from the approval criteria for Coreg CR®. This is actually documented in the minutes as follows "**Board Decision:** The Board approved the MHP recommendations noted above with the requested addition of "unable to tolerate" carvedilol IR to the heart failure indication." Clarification was also asked for regarding the required first line therapies to have been tried prior to approval of Coreg CR®.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Specialty Pharmacy Requests for Proposals: Due to the number of complex proposals received and the time required to appropriately review them, it was decided that Synagis® will not be handled by specialty pharmacy for this RSV season. Synagis® may be obtained through the pharmacies used previously.

4. Medical Director Update: *Erin Reisfeld, M.D. – Medical Director, OVHA*

- Nothing to report this month.

5. Follow-up items from Previous Meeting: *David Calabrese, R.Ph., MedMetrics Health Partners (MHP)*

- Biosimilar Products/Follow-On Proteins
  At the request of the DUR board at the September meeting, a summary review of biosimilar products and their possible impact on the marketplace was presented. The difference between biosimilar products and follow-on proteins was also discussed.

Public Comment: No public comment.

Board Decision: None needed.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Brovana® Nebulization Solution (arformoterol tartrate) – Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient is unable to use a non-nebulized long-acting bronchodilator/anticholinergic (Advair, Serevent or Spiriva) due to a physical limitation OR the patient has had a documented side effect, allergy, or treatment failure with non-nebulized long-acting bronchodilators/anticholinergics. A quantity limit of 2 vials/day was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations as described.

- Reclast® Injection (zoledronic acid) – Not recommended for addition to the PDL. Recommendations for criteria for coverage for the treatment of osteoporosis would include that the patient has a diagnosis/indication of postmenopausal osteoporosis AND the patient has had a documented side effect or treatment failure to a preferred bisphosphonate. Treatment failure is defined as documented continued bone loss after two or more years despite treatment with the bisphosphonate. A quantity limit of one 5 mg dose per year was recommended. It was also recommended that PA be required in the medical benefit for this medication as well. For the treatment of Paget's disease, the criteria for coverage would be that the patient has a diagnosis of Paget's disease.

Public Comment: *James ONeil, Novartis* – Commented that studies have only been done in men for the indication of Paget's disease (but not osteoporosis). Clinical outcome statistics were also presented.

Board Decision: The Board approved the MHP recommendations noted above. The Board requested further information on the duration of the noted drug interactions at the next Board meeting.

- Altabax® Ointment (retapamulin) – Not recommended for addition to the PDL. Criteria for coverage would be that the patient is being treated for impetigo and the patient has had a documented side effect, allergy, or treatment failure with mupirocin or Bactroban®.

Public Comment: Scott Mosher, GSK – Commented on the lack of development of bacterial resistance to retapamulin in-vitro and cost comparisons with other agents.

Board Decision: The Board approved the MHP recommendations noted above with addition of "and MRSA (methicillin resistant staph aureus) has been ruled out by culture".

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*

- Anti-Infectives: Antibioics: Cephalosporins
  The 3 generations of oral cephalosporins were divided by dosage forms so that preferred and PA requiring choices would be clear. The age restrictions on suspension dosage forms were removed as there are few requests for suspensions outside of the pediatric population that are unreasonable. Criteria for approval of a non-preferred agent include side effect, allergy or treatment failure to a similar dosage form in the respective cephalosporin generation. Criteria for approval of a branded product with a generic available include a trial of the generic product. Patients started on non-preferred products without generic equivalents during a hospitalization will be able to complete their course of therapy.

Public Comment: No public comment.

Board Decision: The updated table and revised clinical criteria were unanimously accepted as presented.

- Anti-Infectives: Antibiotics: Quinolones:
  The criteria for PA requiring products was clarified so as to be more specific. Patients started on non-preferred products without generic equivalents during a hospitalization will be able to complete their course of therapy. Quantity limits were removed from all products as most requests to exceed the specified quantity limits were reasonable.

Public Comment: No public comment.

Board Decision: The updated table and revised criteria were unanimously accepted.

- Chemical Dependency: Buprenorphine:
  While preliminary discussions of these criteria have begun, a complete listing of clinical criteria will be presented at next month's DUR Board meeting.

- Anti-Hypertensives: Beta-Blockers:
  The criteria for approval of a non-preferred agent have been revised to read "The patient has had a documented side effect, allergy, or treatment failure to at least one preferred drug. (If a medication has an AB rated generic, the trial must be the generic formulation.)" Additionally, the table has been divided into single agent beta-blockers and beta-blockers in combination with diuretics.

Public Comment: No public comment.

Board Decision: The Board approved the updated table and revised clinical criteria as recommended.

- Anti-Hypertensives: Calcium Channel Blockers:
  Criteria for approval of non-preferred products were clarified to read "The patient has had a documented side effect, allergy, or treatment failure to at least one preferred drug. (If a medication has an AB rated generic, the trial must be the generic formulation.)". Additionally, criteria for approval of Caduet® now reads identically to the criteria in the Lipotropic: Miscellaneous/Combination category.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Coronary Vasodilators/Antianginals: Oral and Topical:
  Criteria for approval of non-preferred products were clarified to specify the appropriate preferred products that are required to have been tried first (rather than any preferred product).

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously approved.

- Gastrointestinals: Histamine-2 Receptor Antagonists:
  Criteria for approval of non-preferred products were clarified to specify the appropriate preferred products that are required to have been tried first (rather than any preferred product).

Public Comment: No public comment.

Board Decision: The revised clinical criteria were accepted as presented.

- Ossification Enhancing Agents:
  The table was divided into oral bisphosphonates, injectable bisphosphonates and other products. It was recommended that injectable Boniva® therapy require PA due to its higher cost than the oral bisphosphonates with a quantity limit of four 3 mg doses per year. This PA should be required in both the pharmacy and medical benefits.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Platelet Inhibitors:
  The table was divided into aggregation inhibitors and other platelet inhibitors. Recommended criteria are now more specific as to the appropriate first line agents which are either the generic products or the individual components of combination products.

Public Comment: No public comment.

Board Decision: The revised clinical criteria and table were unanimously accepted.

- Pulmonary: Inhaled Glucocorticoids:
  The table was divided into metered dose inhalers-single agents, metered dose inhalers-combination products and nebulizer solutions to make the preferred choices more readily evident. Criteria for approval of PA requiring single agent metered dose inhalers were clarified to read "The patient has been started and stablized on the medication or the patient has had a documented side effect, allergy, or treatment failure to at least two preferred agents".

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted with the addition of the omitted word "Diskus" after Advair.

- Pulmonary: Nasal Glucocorticoids:
  Criteria were proposed for non-preferred agents. Due to the variety of preferred products, the criteria were revised to read "The patient has had a documented side effect, allergy, or treatment failure to at least two preferred nasal glucocorticoids. If a product has an AB rated generic, one trial must be the generic formulation."

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

8. New Drug Classes:

No new drug classes were presented at this meeting.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Suboxone®/Subutex®
  Approximately 12 % of all buprenorphine prescriptions are for Subutex® (buprenorphine alone) rather than Suboxone® (buprenorphine/naloxone combination). There is concern that Subutex® is more likely to be abused than Suboxone® and should be limited primarily to use in pregnant women. Clinical criteria will be brought forward at the next DUR Board meeting.

Public Comment: No public comment.

Board Decision: None needed.

10. Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. A variety of products released on the market are not in a drug class that is currently managed or are not specifically addressed in the PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are temporarily blocked and brought to the DUR Board on a periodic basis for approval of permanent block or a decision to unblock. The presented table highlights drug products blocked from drug files dated 08/16/07 - 09/13/07. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Fentora® (fentanyl buccal tablets): The FDA issued a Public Health Advisory and a Healthcare Professional Sheet to alert healthcare professionals and consumers regarding concerns over the use of Fentora® (fentanyl buccal) tablets after recent reports of deaths and other adverse events. The deaths reported were the result of improper selection of patients, dosing, or improper product substitution. The previously established clinical criteria for Fentora® were reviewed. It was recommended that there be no criteria changes in response to this FDA alert at this time. However, it was recommended that the requirement for approval of the initial PA request by the medical director be removed so that the medical director would continue to be available to evaluate second reconsideration requests. It was also recommended that the alert be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

- Bisphosphonates: The FDA issued an early communication about the ongoing review of new safety data regarding the association of atrial fibrillation with the use of bisphosphonates. The FDA reviewed spontaneous postmarketing reports of atrial fibrillation reported in association with oral and intravenous bisphosphonates and did not identify a population of bisphosphonate users at increased risk of atrial fibrillation. The recommendation is that no action is required on the part of the DUR Board in response to this communication. The communication will be posted on the OVHA pharmacy web site.
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Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

Other

- Synagis It was recommended that the PA form be modified. The form now reads that indications outside of the OVHA approved indications require approval by the medical director. The recommendation is that the clause "requires review by OVHA medical director" be removed. The request for PA will be evaluated according to the established criteria by the MedMetrics Clinical Call Center. The OVHA medical director will be available for Synagis second reconsideration requests.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

13. Adjourn: Meeting adjourned at 9:02 p.m.

Next DUR Board Meeting
Tuesday, November 13, 2007
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.